

REMARKS

By this amendment, the status of the claims is claims 2, 8, 9a d 11 to 18 cancelled; claims 1 and 3 amended; dependent claims 4 -7 and 10 unchanged; and new claims 19 to 25 added. Support for the new claims and the amendments are set forth below.

Reconsideration of the application is requested. All remaining claims including new claims 19 to 25, are fully supported by the disclosure of the specification. The remaining claims are fully supported by the specification and recite the invention which the applicant clearly had in mind at the time of presenting the application, as is abundantly evident from the specification. The remaining claims have taken into account the requirements of 35 USC § 112, first and second paragraphs, and fully comply with these requirements.

The invention, as claimed, concerns a method of treating extreme physical stress in a human. The method comprises the steps of treating a human, who has exercised to near physical functional capacity, and thereby is experiencing extreme physical stress, by having the human consume at least 50 mg of L-theanine. The fact of extreme physical stress is evidenced by raised serum prolactin levels in the human. Following consumption by the human of the L-theanine, the extremely physically stressed human is rested for a period of 30 minutes. During this relatively short time of 30 minutes the peripheral controls of the human, including the raised serum prolactin levels are reduced, and are increasingly coupled to the human central nervous controls including neurotransmitters, dopamine, epinephrine, norepinephrine and serotonin, which are substantially unaffected. In this manner, the complete recovery of the human is greatly accelerated from being extremely physically stressed to complete regeneration, as proven by the evidence submitted herewith in the form of a Rule 132 declaration with attached Exhibit detailing testing and clinical results (discussed below).

In the Office action, the Examiner rejected claims 1 and 3-18 as being unpatentable over Juneja et al., "L-theanine—a unique amino acid of green tea and its relaxation effect in humans," Trends in Food Science & Technology (hereinafter "Juneja Article"). The Juneja Article teaches ingesting a 200 mg dosage of L-theanine to promote relaxation as measured by the generation of α brain waves in humans. The Juneja Article on page 201 shows that an injection of L-theanine can relax a spontaneously hypertensive rat (SHR).

Also cited were Kanamichi et al., JP 07-184923, which shows consuming L-theanine to

improve learning efficiency; Wataru et al. '442, which teaches a method for mitigating mental and physical diseases due to stress by ingesting L-theanine; and Fischer et al. EP 1 275 309, cited for stress relaxation, as a cure for insomnia. All of these references are concerned with alleviation of stress of a mental nature, such as anxiety, to induce relaxation and enhance learning, dealing with disease, or as a cure for insomnia. All of these references deal with mental stress, all take more than about 2 hours for the mental stress to be alleviated, and none of them disclose or teach the applicability of L-theanine as a treatment for extreme physical stress caused by exercise to near physical functional capacity in order to obtain complete regeneration and restore the individual to a normal unstressed physical condition in 30 minutes.

Submitted herewith is strong evidence proving the novelty, unobviousness, utility, efficacy and unexpected results of the present invention as now claimed. As noted above, the evidence is in the form of a declaration under Rule 132 with a lengthy exhibit, see Attachment, that details clinical evidence of the efficacy of the claimed method, and fully supports the description in the specification. The declaration proves that the applicants not only had the claimed invention (fully described in the specification) in their possession at the time of filing the application, but that the inventors had made an actual reduction to practice showing that the claimed invention was operative for the purpose intended. The declaration and supporting exhibit are strong evidence of the patentability of the claimed method.

To demonstrate the support of the specification, claim 19 is taken as representative of the remaining claims, and there now follows a claim chart of claim 19 showing the specification support in great detail.

1. A claim chart has been prepared for claim 19 showing that each limitation of claim 19 is fully supported by the specification, and the following quoted paragraphs of the specification show clearly and unambiguously the support for each and every limitation in the claim. Note particularly paragraphs [0008], [0016], [0024] and [0026] of the specification, which characterize the present invention.

**PARAGRAPH CITATIONS OF
SPECIFICATION IN SUPPORT OF
CLAIM LIMITATIONS**

Claim 19. (New)

A method of treating extreme physical stress in a human comprising the steps of

SUMMARY OF THE INVENTION
[0008]The present invention provides a

	<p>method for treating a person under extreme stress, either physical or mental, with at least 50 mg of L-Theanine for purpose of acceleration of regeneration.</p> <p>[0016] It is to be noted that the present invention provides a method to substantially accelerate the natural regeneration process after severe or extreme physical and / or mental stressing of a human.</p> <p>[0024] The investigation model is based on the production of physical stress by means of almost maximum bicycle ergometry as a method which is independent of surroundings, reproducible, reliable and exactly meterable individually according to a pre-test, and which triggers well-researched adaptation reactions.</p> <p>Investigation design and methods</p> <p>[0026] The bicycle ergometry is effected as a multi-stage test with increase up to near maximum functional capacity. The stage height and the maximum performance is determined in a pre-test, which proceeds starting from 50 watts with increase by 50 watts every 3 minutes up to physical exhaustion. The last stage lasting 3 minutes is the criterion for the actual test stress. It is reached there in 4 equal incremental stages each of 3 minutes and then as the fifth stage, 4 minutes are taken. (Variation possibilities: ramp stress, maximum steady state).</p>
treating a human, exercised to near physical functional capacity and who is experiencing extreme physical stress as evidenced by raised serum prolactin levels in the human,	<p>SUMMARY OF THE INVENTION</p> <p>[0008] The present invention provides a method for treating a person under extreme stress, either physical or mental, with at least 50 mg of L-Theanine for purpose of acceleration of regeneration.</p> <p>[0016] It is to be noted that the present invention provides a method to substantially accelerate the natural regeneration process after severe or extreme physical and / or mental stressing</p>

of a human.

[0024] The investigation model is based on the production of physical stress by means of almost maximum bicycle ergometry as a method which is independent of surroundings, reproducible, reliable and exactly meterable individually according to a pre-test, and which triggers well-researched adaptation reactions.

Investigation design and methods

[0026] The bicycle ergometry is effected as a multi-stage test with increase up to near maximum functional capacity. The stage height and the maximum performance is determined in a pre-test, which proceeds starting from 50 watts with increase by 50 watts every 3 minutes up to physical exhaustion. The last stage lasting 3 minutes is the criterion for the actual test stress. It is reached there in 4 equal incremental stages each of 3 minutes and then as the fifth stage, 4 minutes are taken. (Variation possibilities: ramp stress, maximum steady state).

[0025] Measurement of the hypophysen hormone prolactin in the blood serum, which after physical stress reacts like a stress hormone, plays a particular part in the selection of the hormonal parameters, since it is under the control of the central neurotransmitters dopamine (inhibits secretion) and serotonin (promotes release) and thus may reflect the central situation of these two systems. The concentrations of the catecholamines dopamine, noradrenalin and adrenalin in the blood plasma with their different origins (sympathetic ganglia, adrenal medulla) and their effects on circulation and metabolism are selected as further stress parameters from the peripheral ergotropic sympathetic system, and the serum level of the metabolism-stabilising and immune function-controlling adrenal cortex hormone cortisol. Measurement of serotonin in the blood serum may be used by way of supplement, even if the origin of the serotonin measured in the periphery cannot be assigned exactly. For longer

	<p>observation periods, the rates of deposition of the degradation products of catecholamines and serotonin in the urine may also be informative.</p>
consuming by the human of at least 50 mg of L-theanine,	<p>[0027] The first measurement is effected immediately after the end of stress, the test drink is then administered and the recovery phase introduced in standardised manner (usually while lying in a separate peaceful darkened room). Further measurements are effected up to 2 hours after administration of the drink, wherein focus must be directed towards the known or to be foreseen uptake and distribution rate of the test substance into the brain.</p> <p>Results of the investigation on the effect of L-theanine-containing drinks</p> <p>[0028] Drinks with 0 and 50 and 200 mg of L-theanine tasting the same and looking identical were investigated in double-blind manner controlled by placebo under exactly the same conditions according to the above investigation model.</p> <p>[0029] Due to physical near maximum stress, there is in the EEG a rise in electrical performance in all frequency ranges and displacement in the spectral performance density to higher frequencies.</p>
and then resting the human for a period of 30 minutes,	<p>[0027] The first measurement is effected immediately after the end of stress, the test drink is then administered and the recovery phase introduced in standardised manner (usually while lying in a separate peaceful darkened room). Further measurements are effected up to 2 hours after administration of the drink, wherein focus must be directed towards the known or to be foreseen uptake and distribution rate of the test substance into the brain.</p> <p>[0040] Usually this regeneration process of the human brain after stressing takes between one and two hours. When a dose of at least 50 mg L-Theanine is administered after the stressing, the natural regeneration process is substantially accelerated and</p>

	<p>takes only about 30 minutes. This substantial acceleration of the natural regeneration process after stressing is due to the acceleration of the physiological regeneration mechanisms by the L-Theanine.</p>
<p>during which time the peripheral controls of the human including the raised serum prolactin levels are reduced and are increasingly coupled to the human central nervous controls including neurotransmitters, dopamine, epinephrine, norepinephrine and serotonin, which are substantially unaffected,</p>	<p>[0025] Measurement of the hypophysen hormone prolactin in the blood serum, which after physical stress reacts like a stress hormone, plays a particular part in the selection of the hormonal parameters, since it is under the control of the central neurotransmitters dopamine (inhibits secretion) and serotonin (promotes release) and thus may reflect the central situation of these two systems. The concentrations of the catecholamines dopamine, noradrenalin and adrenalin in the blood plasma with their different origins (sympathetic ganglia, adrenal medulla) and their effects on circulation and metabolism are selected as further stress parameters from the peripheral ergotropic sympathetic system, and the serum level of the metabolism-stabilising and immune function-controlling adrenal cortex hormone cortisol. Measurement of serotonin in the blood serum may be used by way of supplement, even if the origin of the serotonin measured in the periphery cannot be assigned exactly. For longer observation periods, the rates of deposition of the degradation products of catecholamines and serotonin in the urine may also be informative.</p> <p>[0035] L-Theanine in the dose range 50 to 200 mg does not trigger quantitative and fundamental changes in physiological sequences of down-regulation after stress in the pharmacological sense, but acts to accelerate the processes of switching from stress to recovery, thus supports switching into the relaxation phase after stress in the sense of promoting regeneration. Due to the changed correlations and the effect on the prolactin level, analogously to results from animal tests known from the literature, it may be assumed that the mechanisms lie in the central</p>

	<p>neurotransmitter system and at the switch points between central electrical brain activity and the peripheral hormonal control and regulating system. The accelerated drop in activity in the rapid electrical frequency ranges in the areas of processing sensory stimuli and in the region of switching electrical performances in the cerebral cortex to hormonal regulation proposals, the shift to other stress hormones but while retaining the hormonal reactivity, is presumably particularly relaxation-promoting.</p>
thereby accelerating recovery of the human from extreme physical stress to complete regeneration.	<p>[0017] Usually the duration which is required for full regeneration after stressing is about one to two hours. In accordance with the invention, a dose of at least 50 mg L-Theanine is administered after the stressing by the person ingesting or drinking a food containing the L-Theanine. This way the regeneration process is substantially accelerated. For example the natural regeneration process can be shortened to about 30 minutes.</p> <p>[0040] Usually this regeneration process of the human brain after stressing takes between one and two hours. When a dose of at least 50 mg L-Theanine is administered after the stressing, the natural regeneration process is substantially accelerated and takes only about 30 minutes. This substantial acceleration of the natural regeneration process after stressing is due to the acceleration of the physiological regeneration mechanisms by the L-Theanine.</p>

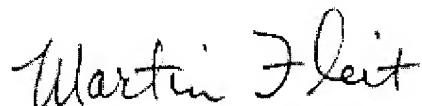
Independent new claim 20 is reproduced here, and it is readily apparent that claim 20 is supported by the same paragraphs of the specification noted in conjunction with the claim chart of claim 19 above. Also, the amendments to claims 1 and 3 are likewise supported by the same paragraphs of the specification.

"20. (New) A method for accelerating recovery of humans experiencing extreme physical stress to near functional capacity comprising feeding a human experiencing extreme physical stress near physical functional capacity from about 50mg to about 200 mg of L-theanine mixed in a foodstuff or drink, and then, following consumption of the mixed foodstuff or drink, resting the human, for a period of 30 minutes to obtain complete regeneration of the human to an unstressed physical condition."

In light of the foregoing remarks and the supporting declaration showing a reduction to practice of the invention, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 7390-X03-020).

Respectfully submitted,



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